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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/216,609 12/21/98 HANSEN

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HM22/0329

EXAMINER

SUN HOFFMAN, L.

ART UNIT

PAPER NUMBER

1642

DATE MAILED:

03/29/00

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trad marks**

# Office Action Summary

Application No.  
09/216,609

Applicant(s)  
Hansen H. J.

Examiner  
Lin Sun-Hoffman

Group Art Unit  
1642



☐ Responsive to communication(s) filed on \_\_\_\_\_.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 1 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 1-54 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☐ Claim(s) \_\_\_\_\_ is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☒ Claims 1-54 are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been  
☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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*Election/Restriction*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-54, drawn to a method for treating a tumor, classified in class 424, subclass 130.1+, 178.1+, 94.1+, 277.1
  - II. Claims 1-54, drawn to a method for treating an infectious lesion or parasitic lesion, classified in class 424, subclass 130.1+, 178.1+, 94.1+.
  - III. Claims 1-54, drawn to a method for treating a fibrin clot, classified in class 424, subclass 130.1+, 178.1+, 94.1+.
  - IV. Claims 1-54, drawn to a method for treating myocardial infarctions, classified in class 424, subclass 130.1+, 178.1+, 94.1+.
  - V. Claims 1-54, drawn to a method for treating atherosclerotic plaques, classified in class 424, subclass 130.1+, 178.1+, 94.1+.
  - VI. Claims 1-54, drawn to a method for treating noncancerous cells and damaged normal cells, classified in class 424, subclass 130.1+, 178.1+, 94.1+.
2. The inventions are distinct, each from the other because of the following reasons: the inventions of Groups I-IV are materially distinct methods which differ at least in objectives, method steps, reagents and/or dosages and/or schedules used, response variables, and criteria for success.

Claims 1-54 are generic to a plurality of disclosed patentably distinct species comprising

- I. Target proteins: (applicant should elect on species even among the Markush group)
  - antibody or conjugated antibody (claim 2)

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- fusion protein (Claim 3)
- covalent conjugate of at least two single chain antibodies (claim 4)
- hMN-14 and anti-human-beta-glucuronidase (claim 9)
- targeting protein-enzyme conjugates with radioisotope labeling or MRI

enhancing agents (claim 32)

- targeting protein-enzyme conjugate is selected from the groups consisting of radiocleotides, drugs, toxins and boron addends (claim 34).
- targeting protein-enzyme conjugates with a radionucleotide label selected from the group consisting of I-131, I-125 and At-211 (claim 35).

II. Enzymes:(applicant should elect one group even among the Markush group)

- esterase, proteases, glucuronidase, dextranase, cellulase, glucosidase (claim 5)
- Carboxyesterase (claim 6)
- beta-glucuronidase (claims 8. 9)
- Dextranase and cellulase (claim 11)
- alkaline phosphatase, beta-lactamase and carboxypeptidase G2 (claim 12).
- cathepsin (claim 21).

III. Prodrug:(applicant should elect one group even among the Markush group)

- CPT-11(claims 7, 8)
- aminodextran or polylysine carrier (claim 11).
- benzoic or phenolic or anilic derivative of mustard (claim 15).

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- Glucuronide conjugate (claim 16)
- dextran, carboxymethylcellulose or a polypeptide (claim 18)
- polyethylene glycol conjugates (claim 19)
- polymer (claim 17)

IV. Therapeutic agent: (Applicant should elect one group even among the Markush group)

- boron addend (claims 42, 43)
- beta-or alpha-emitting radioisotope, a drug, a toxin, a vasodilator, a cytokine, a photosensitizer or a radiosensitizer (claim 44).
- camptothecin (claim 45)

V. Target site:

- If elect tumor treatment, applicant should further elect a specific tumor marker: MUC1, sTn, Le(y), PMSA, Her2/neu, CD220, GM2 and GD3, CSAp and DNA histone (claims 47, 48)

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

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Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

### **3. Fax information Insert**

**Please Note:** In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-305-3704. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Paula Hutzell, Ph.D., Supervisory Patent Examiner at Paula.Hutzell@uspto.gov or 703-308-4310. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lin Sun-Hoffman, Ph.D., whose telephone number is (703)-308-7552. The examiner can normally be reached on Monday to Friday from 7:30 am to 4:00 pm Eastern Standard Time.

7. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paula Hutzell can be reached on (703) -308-4310. The fax phone number for this Group is (703)-308-4242.

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Lin Sun-Hoffman, Ph.D.

March 24, 2000

A handwritten signature in black ink, appearing to read 'Nancy A. Johnson', with a long horizontal flourish extending to the right.

NANCY A. JOHNSON, PH.D  
PRIMARY EXAMINER